Bayer HealthCare
Diabetes Care

OCT 0 8 2008

510(k) SUMMARY

GLUCOFACTS® *Express* Data Management Software

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is k081996.

Prepared:	August 25, 2008
Submitter:	Bayer HealthCare Diabetes Care
Address:	430 South Beiger Street Mishawaka, IN 46544 Phone (574) 256-3441; FAX (574) 256-3519
Contact:	Roger Sonnenburg, Sr. Manager, Regulatory Affairs
Device:	Trade/Proprietary Name: GLUCOFACTS® *Express* Diabetes Management Software
Common/Usual Name:	Diabetes data management software program.
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75 NBW, JQP
Predicate Device:	Ascensia® Glucofacts® Data Management System, k024234
Device Description:	This software application allows the transfer of blood glucose results, along with time, date, and certain data markers, from a Bayer blood glucose meter to a personal computer through the use of a serial or USB cable. Data analysis includes allowing the home-user or healthcare professional to view the data in five different ways: 1. Electronic logbook where all of the data can be seen 2. Glucose trend of the results by date 3. Daily blood glucose trend (standard day) 4. Weekly blood glucose trend (standard week) 5. Summary chart (histogram or pie chart)
Intended Use:	GLUCOFACTS® *Express* Diabetes Management Software is an over-the-counter software program for use by health care

	professionals and patients with diabetes for transferring blood glucose data from a blood glucose meter to a personal computer for the purpose of viewing and printing reports that display blood glucose readings from Bayer's CONTOUR®, CONTOUR® TS, BREEZE®, and BREEZE®2 blood glucose meters.
Technological Characteristics:	There were no changes to the fundamental scientific technology.
Comparison to Predicate device:	GLUCOFACTS® *Express* Diabetes Management Software is similar in function to the predicate device, Ascensia Glucofacts Data Management System, k024234, but has been updated to make it compatible with the most recent Bayer blood glucose meters and to improve the ease of use.
Assessment of Performance:	The performance was assessed in a study that included 51 people – 43 lay users and eight healthcare professionals. The study showed that the program is easy to use and the results are understandable by the users.
Conclusion:	The results of the verification and validation studies of the GLUCOFACTS® *Express* Diabetes Management Software demonstrated that the product is safe and effective in the hands of lay users and healthcare professionals. The product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 8 2008

Bayer Healthcare, LLC
c/o Mr. Roger Sonnenburg
430 South Beiger St.
Mishawaka, IN 46544

Re: k082486
Trade/Device Name: Glucofacts Express Diabetes Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: September 16, 2008
Received: September 17, 2008

Dear Mr. Sonnenburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082486

Device Name: GLUCOFACTS® *Express* Diabetes Management Software

Indications For Use: GLUCOFACTS® *Express* Diabetes Management Software is an over-the-counter software program for use by persons with diabetes in the home and by healthcare professionals in healthcare facilities to assist with transferring blood glucose data from a blood glucose monitor to a personal computer to allow reviewing and analyzing the data to support effective diabetes management.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K082486